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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,816

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT

PAPER NUMBER

1654

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/583,816	<b>Applicant(s)</b> MONTANARI ET AL.	
	<b>Examiner</b> Jeffrey E. Russel	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-7,9-12 and 15-21 is/are rejected.
- 7) ☒ Claim(s) 8,13 and 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 June 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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1. Applicant's election of the species Tyr-Arg in the reply filed on May 4, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 3 and 4 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 4, 2009.

2. The Sequence Listing filed February 5, 2009 is approved.

3. The drawings are objected to because in Figure 1, the y-axis label appears to include Italian words. The label needs to be translated into English. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and

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informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The disclosure is objected to because of the following informalities: There is no Brief Description of the Drawings as is required by 37 CFR 1.74. Page 8, line 12, of the specification refers to “claim 1”. Because of the likelihood of claim amendment, claim cancellation, and claim re-numbering during prosecution of an application, the specification should be re-written in order to avoid any reference to particular claim numbers. SEQ ID NOS must be inserted after each occurrence in the specification of an amino acid sequence subject to the sequence disclosure rules. See 37 CFR 1.821(d). Such sequences occur at, e.g., pages 9, 10, 15, 16, 20, 21, and 25 of the specification. Appropriate correction is required.

5. Claims 5-7 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis in the claims for the phrase “said dipeptide” in claims 5 and 6. It may be that these two claims should instead depend upon claim 2, which explicitly recites dipeptides. There is no antecedent basis in the claims for the phrase “the association of sodium-potassium micro-elements” in claim 10. None of the previous claims mention an “association” of micro-elements or explicitly recite a combination of sodium and potassium micro-elements.

6. Claim 1, 2, and 5-21 are objected to because of the following informalities: At claim 1, lines 3 and 4, “the” should be deleted in order to avoid issues of lack of antecedent basis. SEQ ID NOS must be inserted after those amino acid sequences occurring in the claims which are subject to the sequence disclosure rules. See 37 CFR 1.821(d). Such sequences occur in claims

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8, 13, and 14. At claim 8, line 3; claim 13, line 3; and claim 14, line 6; the numeral “2” in the C-terminal amide group should be changed to a subscript. At claim 9, line 2, and claim 12, line 2, “at least one” should be inserted before “micro-element”, because claims 9 and 12 recite, at least in part, combinations of micro-elements. At claim 10, line 2, the comma after “to” should be deleted. At claim 19, line 2, “the” (second occurrence) should be deleted in order to avoid issues of lack of antecedent basis. Appropriate correction is required.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. *Joy Technologies Inc. v. Quigg*, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. *In re Hoeschele*, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. *In re Clinton*, 188 USPQ 365, 367 (CCPA 1976); *In re Thompson*, 192 USPQ 275, 277 (CCPA 1976).

8. Claims 1, 2, 5-7, 9, 15, 19, and 21 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Lintner et al (U.S. Patent Application Publication 2004/0120918) as evidenced by Lintner (U.S. Patent Application Publication 2004/0132667). Lintner et al teach a composition comprising potassium sorbate, sodium hydroxide, and Calmosensine®. Potassium sorbate and sodium hydroxide correspond to Applicants' micro-element. The composition is in the form of a cream. Lintner et al's compositions in general are intended to treat wrinkles in facial skin and hands and signs of skin aging, and can be in any physical form. See, e.g., the Abstract; paragraphs [0035] and [0297]; and Example 4, paragraph [0317]. Lintner '667 teaches (see paragraph [0095]) that the Calmosensine® of Lintner et al is a synonym for N-Acetyl-Tyr-Arg-hexadecyl ester, which is Applicants' elected and preferred dipeptide species. The facial wrinkles due to skin aging taught by Lintner et al correspond to Applicants' expression wrinkles. Because of the identity of components and method steps between Lintner et al and Applicants' claimed convention, inherently the N-Acetyl-Tyr-Arg-hexadecyl ester of Lintner et al will exhibit decontracting action on muscular fibers present in wrinkles, and inherently the potassium sorbate and sodium hydroxide of Linter et al will reduce contraction of a muscular fiber present in wrinkles, to the same extent claimed by Applicants. Sufficient evidence of similarity is

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deemed to be present between the composition and method of Lintner et al and Applicants' claimed compositions and methods to shift the burden to Applicants to provide evidence that the claimed compositions and methods are unobviously different than those of Lintner et al. Note that more fully disclosing a biochemical mechanism by which a prior art composition or method works, or disclosure of properties inherent in a prior art composition, does not constitute a basis for patentability.

9. Claim 16 is rejected under 35 U.S.C. 103(a) as being obvious over Lintner et al (U.S. Patent Application Publication 2004/0120918) as evidenced by Lintner (U.S. Patent Application Publication 0132/667). Application of Lintner et al and Lintner '667 is the same as in the above rejection of claims 1, 2, 5-7, 9, 15, 19, and 21. Lintner et al do not specifically exemplify a composition comprising Calmosensine® in the form of liposomes, although in general Lintner et al teach that their compositions can be administered in the form of liposomes. See, e.g., paragraph [0059] and claim 32. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to administer the Calmosensine®-containing compositions of Lintner et al in the form of liposomes, because Lintner et al teach that liposomes have general utility for administering their compositions, and because the physical form of Lintner et al's active agents would not have been expected to affect materially the biochemical effects which Lintner et al's active agents have on wrinkles.

10. Claims 9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being obvious in view of Lintner et al (U.S. Patent Application Publication 2004/0120918) as evidenced by Lintner (U.S. Patent Application Publication 2004/0132667) as applied against claims 1, 2, 5-7, 9, 15, 19, and 21 above, and further in view of Sojka (U.S. Patent Application Publication 2005/0002996), Patt

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(U.S. Patent Application Publication 2006/0052287), and Renault (U.S. Patent Application Publication 2004/0147443). Lintner et al do not teach the inclusion of sodium gluconate, potassium gluconate, and magnesium gluconate in their compositions. Sojka teach sodium gluconate to be a known skin conditioning agent. See, e.g., paragraph [0056]. Patt teach potassium gluconate to be a known skin protectant. See paragraph [0048] and page 18, lines 7-10, of its provisional application 60/602,715. Renault teaches compositions comprising magnesium gluconate for the treatment of expression wrinkles. See, e.g., paragraphs [0085] and [0104], and Examples 1-2. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to include the sodium gluconate, potassium gluconate, and magnesium gluconate of Sojka, Patt, and Renault in the compositions of Lintner et al, because each of the components is known to be useful in treating skin, and because the use of combinations of known skin treating components in cosmetic compositions is routine in the cosmetic art.

11. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being obvious in view of Lintner et al (U.S. Patent Application Publication 2004/0120918) as evidenced by Lintner (U.S. Patent Application Publication 2004/0132667) as applied against claims 1, 2, 5-7, 9, 15, 19, and 21 above, and further in view of Laversanne et al (U.S. Patent No. 6,277,404). Lintner et al teach that their compositions can be administered in any physical form, but do not teach a physical form which is a multilamellar liposome having a dimension ranging from 150-500 nm. Laversanne et al teach substantially spherical multilamellar vesicles, i.e. liposomes, having a dimension of 0.1 to 100  $\mu\text{m}$ , i.e. 100 to 100,000 nm, and carrying a positive charge so that a cosmetically active agent will more readily adhere to the skin of a subject being treated. Active

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agents to be administered include peptides. See, e.g., the Abstract; column 4, lines 14-17 and 20-30; and column 7, lines 20-25. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to administer the composition of Lintner et al in the form of a multilamellar vesicle as taught by Laversanne et al, because Lintner et al's compositions are not required to be administered in any particular physical form, and because Laversanne et al show that multilamellar vesicles are known to be useful for applying cosmetic agents to skin and can have the benefit of allowing better adherence of the cosmetic agents to the skin.

12. Claim 20 is rejected under 35 U.S.C. 103(a) as being obvious in view of Lintner et al (U.S. Patent Application Publication 2004/0120918) as evidenced by Lintner (U.S. Patent Application Publication 2004/0132667) as applied against claims 1, 2, 5-7, 9, 15, 19, and 21 above, and further in view of Donovan (U.S. Patent Application Publication 2005/0074461) or the Japanese Patent Application 2004-197234. Lintner et al teach a composition for treating wrinkles in facial skin and hands, but do not teach Applicants' claimed apparatus for administering the composition. Donovan teaches administering compositions topically to a person's skin using syringe without needles so as to prevent the compositions from contacting the fingers of the person. See paragraph [0073]. The Japanese Patent Application '234 teaches a syringe for applying liquid cosmetics to the skin. See, e.g., the attached abstract. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use the syringes of Donovan or the Japanese Patent Application '234 to apply the composition of Lintner et al, because Donovan and the Japanese Patent Application '234 teach known apparatus for applying cosmetics to skin, the same purpose taught by Lintner et al, and because the

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particular apparatus used to administer Lintner et al's composition would not have been expected to affect materially the cosmetic properties of the composition.

13. Claims 1, 2, 9, 11, 15, 19, and 21 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Renault (U.S. Patent Application Publication 2004/0147443). Renault teaches a composition comprising a peptide and magnesium, whereas the combination of components has synergistic activity with respect to type-L calcium channels, and act to relax muscles which help to cause expression wrinkles. The peptide can comprise 5 amino acids. A preferred source of magnesium is magnesium gluconate. The composition can be in any form normally used in cosmetics, including a cream. See, e.g., paragraphs [0031]-[0033], [0040], [0043], [0085], [0090], [0091], and [0104]; Examples 1-2; and claim 7.

14. Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, and the claim objections set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 13 and 14 would be allowable if rewritten to overcome the claim objections set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

With respect to instant claims 8, 13, and 14, Reers (U.S. Patent No. 5,563,041) is cited as art of interest, teaching a composition comprising a combination of the pentapeptide Gly-Pro-Arg-Pro-Ala and a source of sodium (see Example 2); and Stuber et al (U.S. Patent No.

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5,607,858) is cited as art of interest, teaching the pentapeptide Gly-Pro-Arg-Pro-Ala. However, there is no motivation or any other type of suggestion in the prior art of record to combine these pentapeptides with the dipeptides taught in the references applied above.

With respect to claim 10, Albacarys et al (U.S. Patent No. 6,338,855) is cited as art of interest, teaching anise extracts which have anti-wrinkle, anti-skin atrophy, and/or skin repair activities. See column 19, lines 26 and 48. However, Albacarys et al do not teach an aqueous extract of anise, do not teach an extract of anise fruit (compare page 13, lines 18-20, of Applicants' specification), and do not describe their anise extract as comprising both sodium and potassium.

The French Patent 2,786,693 is cited as art of interest (see especially Example 5), being essentially duplicative of the references applied above.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/  
Primary Examiner, Art Unit 1654

JRussel  
July 16, 2009